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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ABBOTT DIABETES CARE INC. and
ABBOTT LABORATORIES,

Plaintiffs,

v.

ROCHE DIAGNOSTICS CORP., and BAYER
HEALTHCARE LLC,

Defendants.

Case No. C05-03117 MJJ

**JOINT STATEMENT OF
UNDISPUTED FACTS
REGARDING MOTION FOR
SUMMARY JUDGMENT OF
INVALIDITY OF THE '745
PATENT**

Date: December 12, 2007

Time:

Place: Courtroom 11, 19th Floor

Judge: Hon. Martin Jenkins

No.	Fact	Defendants' Evidence
1.	The '745 Patent involves disposable test strips that are used with meters to determine blood glucose concentration. The sample chamber of these test strips includes at least two electrodes, commonly called a working electrode and a counter electrode (as that term is defined in the '745 Patent).	Ex. 1 ('745 Patent) at 7:61-67. ¹
2.	The sample chamber also contains at least two different chemicals, namely, a mediator and an enzyme (collectively known as "reagents").	<i>Id.</i> at Abstract [57].
3.	The '745 Patent discloses at least three ways to determine the concentration of glucose in whole blood: coulometry, potentiometry, and amperometry.	Ex. 1 ('745 Patent) at Abstract [57], 6:12-13, 6:20-29, 7:19-21.
4.	In an amperometric test, the glucose concentration is determined by measuring the current, with the magnitude of the current being proportional to the concentration of glucose.	Ex. 2 (Bard Dep. 10/18/2007) at 291:9-292:11.
5.	Claim 28 of the '745 Patent is limited to amperometric testing.	Ex. 1 ('745 Patent) at 65:1-2.
6.	The '745 Patent discloses at least two different ways of configuring the electrodes. The electrodes can be placed on the same substrate such that they are in a "co-planar" configuration. The electrodes can also be on separate substrates in a facing configuration.	Ex. 1 ('745 Patent) at 3:31-33, 3:51-54, Fig. 2; 3:18-24, 3:46-50, Fig. 1.
7.	The reaction in glucose test strips can produce a current from sources other than glucose, which may adversely affect the accuracy of the measurement. This current is generally called a background signal.	Ex. 3 (Claim Construction Order, filed 4/27/2007) at 25.
8.	Mediator shuttling occurs when a mediator molecule that has given up its electron at the working electrode diffuses to the counter electrode, picks up an electron there, and then travels back to the working electrode and gives up the electron there.	<i>Id.</i> at 27.
9.	The Gotoh '391 Patent was filed on December 15, 1997.	Ex. 4 (Gotoh Patent) at

¹ Exs. 1 to 30 are attached to the Jorjani Declaration ISO Bayer and Roche's Joint Motion for Summary Judgment of Invalidity of the '745 Patent, filed October 26, 2007. Exs. 31 to 44 are attached to the Jorjani Declaration ISO Bayer and Roche's Reply to Their Joint Motion for Summary Judgment of Invalidity of the '745 Patent, filed November 21, 2007.

No.	Fact	Defendants' Evidence
		[22].
10.	Abbott's earliest alleged conception date for the '745 patent is July 30, 1998.	Ex. 5 (Abbott's Supp. Resp. 9/12/2007) at 3 (alleging conception date of July 30, 1998).
11.	Example B1 of Gotoh describes a blood glucose test strip with working and counter electrodes separated by 140 µm (microns), and enzyme and mediator placed on the working electrode. A 1 µL (microliter) sample was added to the strip, and, after a 20-second rest period, a potential was applied for 10 seconds.	Ex. 6 (Bard Dep. 10/19/2007) at 395:15 - 398:10.
12.	Examples B1 and D1 of the Gotoh Patent disclose a "method for determining a concentration of glucose in a sample."	Ex. 4 (Gotoh Patent) at 1:44-58.
13.	Examples B1 and D1 of the Gotoh Patent disclose "contacting a sample with an electrochemical sensor."	Ex. 4 (Gotoh Patent) at 8:24-39, 12:34-50.
14.	Examples B1 and D1 of the Gotoh patent disclose working and counter electrodes "separated by a closest distance no greater than 1000 µm." In examples B1 and D1, both of which have electrodes in a facing configuration, the distance between the electrodes is 140 µm and 230 µm, respectively.	Ex. 4 (Gotoh Patent) at 7:56-8:10, 12:4-33.
15.	The '745 Patent defines "measurement zone" as "a region of the sample chamber sized to contain only that portion of the sample that is to be interrogated during an analyte assay."	Ex. 1 ('745 Patent) at 7:7-9; Ex. 9 (Claim Construction Statement, filed 10/24/2006), Exh. 2 at 1.
16.	Example B1 of the Gotoh patent relates to Figures 6-9.	<i>Id.</i> at 6:63-9:5.
17.	Example D1 of the Gotoh patent relates to Figures 11-14.	<i>Id.</i> at 9:63-13:34.
18.	In its Claim Construction Order, the Court defined the term "adjacent" to mean that the "measurement zone is next to (whether or not touching) both the working electrode and the counter electrodes, with no structure intervening between either electrode and the measurement zone."	Ex. 3 (Claim Construction Order) at 24.
19.	Examples B1 and D1 in the Gotoh patent use an analyte-responsive enzyme (glucose oxidase) and a diffusible mediator (ferricyanide).	Ex. 4 (Gotoh Patent) at 7:58-67, 12:14-21.

No.	Fact	Defendants' Evidence
20.	In the related BD case, the Court construed the term “non-flowing” in a sister patent to mean that the sample is “not moving” during measurement.	Ex. 11 (Claim Construction Order (BD), dated 8/31/2006) at 15-16.
21.	The Court has construed the phrase “background signal that is generated by the redox mediator” as “background signal that is created by the shuttling of the redox mediator back and forth between the working and counter electrodes during the measurement period.”	Ex. 3 (Claim Construction Order) at 26.
22.	Shuttling requires the mediator molecule to travel from the working electrode to the counter electrode and back again.	<i>Id.</i>
23.	According to the ‘745 Patent, no shuttling will occur when the electrodes are spaced far enough apart.	Ex. 1 (‘745 Patent) at 43:49-57.
24.	The $(D_{mt})^{1/2}$ equation disclosed in the ‘745 patent was known in the art prior to the ‘745 Patent.	Ex. 14 (30(b)(6) Dep. of Feldman) at 179:15 - 182:10.
25.	The ‘745 Patent provides an example of how to space the electrodes to diminish shuttling, given a diffusion coefficient between 10^{-5} and 10^{-6} cm ² /s and a test time of 30 seconds.	Ex. 1 (‘745 Patent) at 43:57-62.
26.	Examples B1 and D1 of the Gotoh patent disclose determining the concentration of the glucose using current, <i>i.e.</i> , by amperometry.	Ex. 4 (Gotoh Patent) 8:28, 12:38.
27.	The Heller ‘225 reference was published on August 13, 1998.	Ex. 23 (Heller ‘225 Reference) at 1.
28.	The ‘164 patent and the Heller ‘225 reference contain the same disclosure.	Ex. 7 (Bard Rebuttal Report) at 24 and Ex. 2 (Bard Dep.10/18/2007) at 144:23 - 145:2.
29.	Each claim of the ‘745 patent requires that the measurement zone: (1) be “positioned adjacent to the working electrode and counter electrode”, (2) be “sized to contain a volume of no more than 1 microliter of the sample;” 3) contain an “analyte-responsive enzyme and a diffusible redox mediator;” and 4) hold the sample “in a non-flowing manner[.]”	<i>Id.</i> at 61:47-54.

1 DATED: November 28, 2007

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